

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
26 April 2001 (26.04.2001)

PCT

(10) International Publication Number
WO 01/28607 A1

(51) International Patent Classification⁷: **A61M 3/02**

(74) Agent: GERVASI, Gemma; Notarbartolo & Gervasi S.p.A., Corso di Porta Vittoria, 9, I-20122 Milano (IT).

(21) International Application Number: **PCT/EP00/09985**

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(22) International Filing Date: 11 October 2000 (11.10.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
MI99A002162 15 October 1999 (15.10.1999) IT

(71) Applicant (*for all designated States except US*): MEDICAL INTERNATIONAL LICENSING N.V. [NL/NL]; Penstraat 105, Willemstadt, Curaçao (AN).

(72) Inventor; and

(75) Inventor/Applicant (*for US only*): MEZZOLI, Giorgio [IT/IT]; Via Ricci Curbastro, 56/1, I-48022 Lugo (IT).

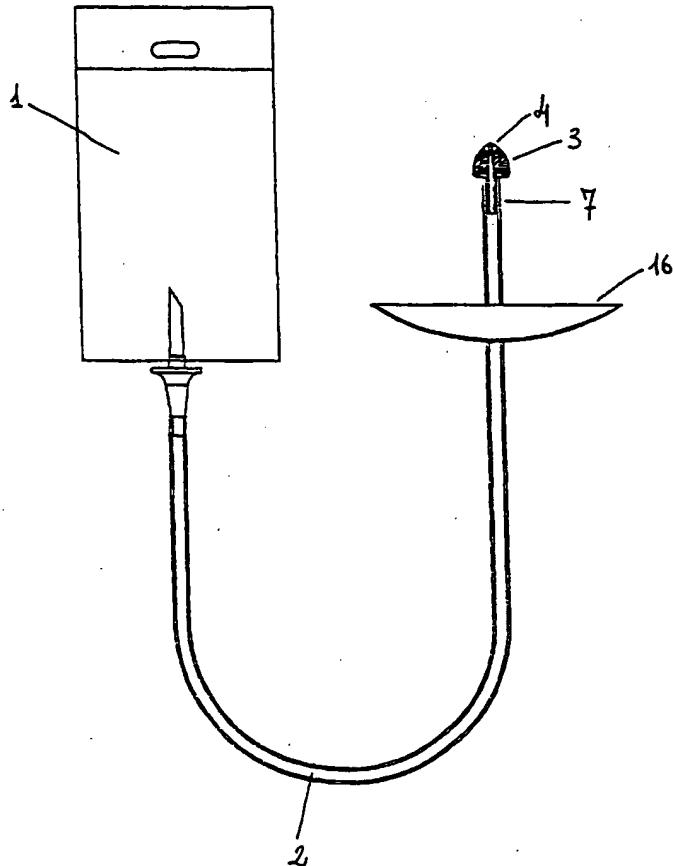
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *With international search report.*

[Continued on next page]

(54) Title: A DEVICE FOR WASHING OR IRRIGATION OF THE VAGINAL CAVITY AND THE URETHRAL OSTIUM



(57) Abstract: A device is disclosed for washing or irrigating the vaginal cavity and the urethral ostium having a flexible container for the washing solution, an olive-shaped nozzle with apical, radial and basal ejection openings. The nozzle further comprises a stem to be inserted into the tube, to which a disc or cup is also fitted.



— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

"A DEVICE FOR WASHING OR IRRIGATION OF THE VAGINAL CAVITY AND THE URETHRAL OSTIUM"

SCOPE OF THE INVENTION

The present invention refers to a device for washing or irrigation of the vaginal cavity and the urethral ostium.

STATE OF THE ART

The vagina is an elongated virtual cavity having an average length of approximately 12 cm. In the proximal part, it is made up of the head of the neck of the uterus and of a recess, the so-called fornix of the vagina; the vaginal cavity presents an H-shaped cross section; the distal part opens outwards with the small and the large labia and contains the outer urethral ostium.

The particular anatomical and physiological situation of the vaginal cavity and its recesses facilitates collection and stagnation of secretions both of a pathological nature and ones due to overproduction of vaginal secretions in parphysiological situations or to the presence of semen following intercourse. These secretions may assume characteristics of particular density so that they prove difficult to remove from the vaginal walls and in particular from the fornix of the vagina, which form pockets where the secretion constantly stagnates. In such cases, the medical therapy using creams and ovules almost always fails in that there remain what amount to "pools" where the pathogenic agents find their ideal habitat for their survival. In addition, the pathological secretions that leave the vaginal ostium, stagnating locally in the interlabial space, in the top part of which the external orifice of the urethra is located, may infect the urinary tract.

Consequently, it is very important that there should be available devices suitable for non-traumatic cleansing of the entire vaginal cavity and of the interlabial space.

The known devices for washing and irrigation of the vaginal cavity, the interlabial space and, hence, of the external orifice of the urethra are represented by a rigid cannula, the maximum length of which is approximately 12 cm, which is to be introduced into the vaginal cavity and is provided, at one end, with a nozzle that presents lateral and/or top openings, and, at the other end, with a compressible container for the washing liquid.

This type of device presents various drawbacks:

- the nozzle through which the washing liquid is distributed within the vaginal cavity is provided with small channels that generate filiform jets and direct them straight onto the vaginal mucosa, in this way exerting a traumatic action on the latter;
- since these jets are filiform, they enable washing only of circumscribed areas and generally fail to reach the fornix of the vagina;
- the nozzle is connected to the container of the washing liquid by means of a rigid cannula, a fact that renders the device not flexible and consequently traumatic when it is introduced into the vaginal cavity and the container of the washing liquid is compressed;
- the maximum length of the rigid cannula is approximately 12 cm, which represents the average length of the vaginal cavity, precisely to prevent possible traumas to the head of the neck of the uterus and to the fornix of the vagina at the moment of insertion of the cannula into the cavity or of its use. In any case, both these manoeuvres (insertion and washing by compression of the container of the liquid) frequently cause discomfort and/or pain on account of tightening of the muscles and/or traumas due to the rigidity of the device;
- throughout the washing operation, in addition to compressing the container with one hand, it is necessary to keep it pushed towards the vaginal cavity so that the cannula remains in position inside the vaginal cavity, a fact that makes the entire operation somewhat inconvenient;
- the known devices do not provide any means to enable washing of the top portion of the interlabial space, where the external urethral orifice is located.

25 SUMMARY OF THE INVENTION

There has now been surprisingly found a device for washing the vaginal cavity and the interlabial space comprising the external ostium of the urethra which enables complete cleansing of the entire area, both internal and external, in a convenient and relaxed position, without causing pain or muscular tightening, without causing any trauma to the vaginal mucosa, and without the user getting her hands wet.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 illustrates the device according to the present invention.

Figures 2a-d illustrate an embodiment of the nozzle that forms part of the device according to the present invention. In particular, Figure 2b shows a longitudinal section; Figures 2a and 2c illustrate, respectively, a top plan view and a bottom plan view; and Figure 2d shows a side view with the tube (2) sectioned longitudinally.

Figures 3a-d illustrate variants of the nozzle of Figure 2.

Figures 4a-d illustrate a further variant of the nozzle forming part of the device according to the present invention. In particular, Figure 4b shows a longitudinal section; Figures 4a and 4c illustrate, respectively, a top plan view and a bottom plan view; and Figure 4d a side view with the tube (1) sectioned longitudinally.

Figure 5a presents a perspective view from below of the same nozzle.

Figures 5b and 5c illustrate another variant of the nozzle forming part of the device according to the present invention, respectively in longitudinal section and in perspective view from below.

Figures 6a-c illustrate, respectively, a bottom plan view, a longitudinal section, and a top plan view of the disk or cup (16).

DESCRIPTION OF THE INVENTION

The device for washing or irrigation of the vaginal cavity and the urethral ostium according to the present invention is made up of a flexible container (1) containing the washing liquid, a flexible tube (2) and an olive-shaped nozzle (3) with an invaginated truncated base with smooth, curved surfaces and without sharp edges, that are designed to facilitate non-traumatic introduction and extraction, the said nozzle (3) being characterized by an apical ejection opening (4) made up of a central body (5) aligned with a central channel (20) of the nozzle (3), and by a multiplicity of radial openings (6) that branch off from it that are designed to form a homogeneous jet shaped as a truncated cone with the base facing upwards, and being further characterized by a stem (7) made up of a body (8) provided with at least one tab (9) or divided into at least one section (14), both these types of structure being L-shaped in an area corresponding to the concave base of the

nozzle (3) so as to form a spacing diaphragm (10) which, once the tube (2) has been inserted, gives rise to at least one basal ejection opening (11), designed to form an annular or circular jet which diverges downwards.

5 Optionally, the tube (2) is provided with a disk or cup (16) preferably removable,

mobile and sliding on the tube (2), and coaxial thereto.

Figure 1 is a schematic illustration of the device according to the present invention.

Figures 2a-d show an embodiment of the device according to the present invention. Figure 2a illustrates a top plan view of the nozzle (3) with the central body (5) and the radial openings (6), that make up the apical opening (4). The central body (5) appears even more clearly visible in Figure 2b. Thanks to its shape and its position, said central body (5) is able to break up the jet arriving from the central cavity (20) of the nozzle (3) and to cause its exit from the radial openings (6) as homogeneous and partially or totally nebulized jets. In fact, the

10 washing liquid, breaks against the central body (5) into a plurality of jets, that, being indirect, are non-traumatic for the vaginal mucosa.

15 Figure 2b also illustrates the structure of the stem (7), with particular regard to the means designed to form the spacing diaphragm (10), which, in the example of embodiment described herein, consist of the L-shaped ends of tabs (9), set longitudinally on the outer wall of the body (8). The tabs (9) and, consequently, the spacing diaphragms (10) are preferably four, as illustrated in Figure 2c. This Figure shows how the tube (2) is fitted on the tabs (9) along the entire body (8) of the stem (7), creating at least one gap (12) – in the case of Figure 2c, four of such gaps – through which part of the washing liquid flows to come out of the basal

20 ejection opening (11) at the level of the separator diaphragm (10) and breaks against an internal oblique wall close to the angle (15) that said oblique wall forms with the bottom wall of the concave base of the nozzle (3), creating a circular, annular jet that is non-traumatic for the vaginal mucosa in that it is indirect. Figure 2d is a side view of the nozzle (3) with the tube (2) sectioned longitudinally so as 25 to illustrate more clearly the external structure of the stem (7), in particular the body (8) and the tabs (9).

Figures 3a and 3b illustrate a variant of the nozzle (3) of Figures 2a-d. Figure 3a shows a longitudinal section of this variant that is characterized by the presence of a multiplicity of protrusions (13), positioned on the bottom wall of the nozzle (3) in areas corresponding to the basal ejection openings (11), designed to favour the "breaking" and thus the partial or total nebulization of the jets of liquid that come out of said openings (11). Also in this case, an indirect jet is produced which is therefore non-traumatic for the vaginal mucosa. Figure 3b affords a perspective view, from below, of the nozzle (3) according to the variant provided with protrusions (13).

Figures 3c and 3d show a cross section of two variants of the stem (7) of Figures 2a-d. In the variant of Figure 3c, the tabs (9) present a T-shaped cross section, whilst in the variant of Figure 3d the T-shaped transverse areas of the tabs (9) are joined in a single integral surface.

Figures 4a-d show another embodiment of the device according to the present invention. Figure 4a illustrates a flat top view of the nozzle (3), with the central body (5) and the radial openings (6), the said structures making up the apical opening (4). The central body (5) is even more clearly visible in Figure 4b. Thanks to its shape and its position, the aforesaid central body (5) is able to break the jet arriving from the central cavity of the nozzle (3) and in this way to cause its exit from the radial openings (6) in a homogeneous and nebulized way. In fact, the washing liquid, by breaking against the central body (5) determines a plurality of jets, which, being indirect, are non-traumatic for the vaginal mucosa.

Figure 4b also illustrates the structure of the stem (7). In this case, the body (8) is divided into at least one longitudinal section (14) the top end of which is L-shaped to form the spacing diaphragm (10). The sections (14) that make up the body (8) are preferably four, as illustrated in Figure 4c. This figure clearly shows how the tube (2) fits on the sections (14) along the body (8) of the stem (7), creating at the level of the concave base of the nozzle (3) at least one ejection opening (11) – in the case of Figure 4c, four of such ejection openings – (illustrated also in Figures 5a and 5c) through which part of the washing liquid comes out. Figure 4d is a side view of the nozzle (3) with the tube (2) sectioned longitudinally so as to show more

clearly the outer structure of the stem (7), in particular the sections (14) of the body (8). Figure 5a illustrates a perspective view, from below, of the nozzle (3) according to the embodiment of Figures 4a-d.

Figures 5b and 5c illustrate a variant of the nozzle (3) of Figures 4a-d. Figure 5b shows a longitudinal section of this variant, which is characterized by the presence of a multiplicity of protrusions (13) positioned on the bottom wall of the nozzle (3) in an area corresponding to the basal ejection openings (11), designed to favour the "breaking" of the jets of liquid that come out of said openings (11), and consequently their homogeneous distribution and their partial or total nebulization, and to generate indirect jets that are non-traumatic for the vaginal mucosa. Figure 5c affords a perspective view, from below, of the nozzle (3) according to the variant provided with protrusions (13).

Figures 6a-c show, respectively, a view from below, a longitudinal section along the major axis (a), and a view from above of the disk or cup (16), optionally present in the device of the present invention, in its concave variant, which is removable from the tube (2). Said device consists of walls (19) along the channel (18) for fitting onto the tube, and of a hole (17) for housing the tube itself.

Washing with the device according to the invention is carried out by introducing the nozzle (3) into the vaginal cavity holding the tube (2) in the hand, until the said nozzle reaches the vicinity of the neck of the uterus of a subject sitting on a bidet or on a toilet or crouching down in a shower or in a bath or some other suitable place, with legs slightly divaricated. Then, the container (1) is compressed manually so as to cause the liquid to flow out into the flexible tube (2) up to the nozzle (3) from which the liquid comes out simultaneously both from the apical opening (4) and from the basal opening (11).

The nozzle of the invention generates two main jets of liquid, one coming out from the apical radial openings (6) and having the shape of a frustum of cone with the major base facing upwards and the other coming out of the basal ejection opening (11) and having an anular or circular shape, both of said jets diverging from said openings. The jets reach diffusely the entire area of the neck of the uterus and of the fornix of the vagina, from which they flow away, together with the products of

washing towards the outside of the vaginal channel. The jets are not conveyed directly onto the vaginal mucosa, but rather in the first place impinge on the internal oblique wall close to in the angle (15) that said wall forms with the bottom wall of the concave basal portion of the nozzle (3) (illustrated in Figures 2b, 3a, 4b and 5b) and, optionally, on the protrusions (13) located at the level of the basal opening (11), and on the central body (5) of the apical opening (4) made up of a multiplicity of openings (6). As regards, in particular, the central body (5), this breaks up the jet, dividing it into a plurality of homogeneous fan-shaped flows having reduced pressure compared to the initial jet from which they derive. When it comes into contact with the walls of the mucosa, the jet, in addition to being distributed homogeneously over the mucosa, has a nebulized nature, and consequently is able to carry out washing of the channel and of the fornix of the vagina without traumatic consequences and without irritation of the mucosae.

Outflow of the liquid is facilitated by the jet that comes out of the basal opening (11), thanks to its divergent and annular or circular nature and to its retrograde direction outwards. In addition, said bottom jet has the function of maintaining in the initial position – namely, in the vicinity of the neck of the uterus – the nozzle (3), which otherwise, on account of the pressure of the top jet against the neck of the uterus, would be sent out of the vaginal channel.

The disk or cup (16), which is optional in the device of the present invention, has a dual function:

1) once the nozzle (3) has been set in position inside the vaginal cavity in the vicinity of the head of the neck of the uterus, the disk or cup (16) is positioned with its major axis (a) parallel to the large labia with the top edge resting just above the urethral opening and with the channel (18) facing downwards so as to allow the washing liquid to flow away;

2) once washing of the vaginal cavity is completed, whilst the cup is held with one hand, the nozzle (3) is drawn out of the vaginal cavity until it is set in a position corresponding to the housing (17) of the tube (2); the disk or cup (16) is set with the major axis (a) parallel to the large labia in a position corresponding to of the urethral opening, which is cleansed by the jets of the apical opening (4) and by

those of the basal opening (11), which impinge and break up on the surface of the disk or cup (16).

CLAIMS

1. A device for washing or irrigation of the vaginal cavity and the urethral ostium consisting of a flexible container (1) containing the washing liquid, a flexible tube (2) and an olive-shaped nozzle (3) having a concave truncated base with smooth curved surfaces and without sharp edges, said nozzle (3) being characterized by an apical ejection opening (4) made up of a central body (5) aligned with a central channel (20) of the nozzle (3), and of a multiplicity of radial openings (6) that branch off from it, and being further characterized by a stem (7) made up of a body (8) which presents, in an area corresponding to the concave truncated base of the nozzle (3), means designed to form a spacing diaphragm (10) which, once inserted in the tube (2), form at least one basal ejection opening (11).
5
2. A device according to Claim 1 provided with a disk or cup (16) set coaxial to the tube (2).
- 10 3. A device according to Claim 2, in which the disk or cup (16) is removable, mobile and slides on the tube (2).
4. A device according to Claim 1, in which the body (8) has at least one tab (9), set longitudinally on the outer surface, the top end of which is L-shaped to form the spacing diaphragm (10).
- 15 5. A device according to Claim 4, in which the tabs (9) have a T-shaped cross section.
6. A device according to Claim 5, in which the transverse areas of the T-shaped tabs (9) join in a single integral surface.
- 20 7. A device according to Claim 4, in which the body (8) is provided with four tabs (9).
8. A device according to Claim 1, in which the body (8) is divided in at least one longitudinal section (14) the top end of which is L-shaped to form the spacing diaphragm (10).
- 25 9. A device according to Claim 8, in which the body (8) is divided into four sections (14).
10. A device according to Claim 1, in which the nozzle (3) is characterized by the

10

presence of a multiplicity of protrusions (13) positioned on the internal concave bottom surface of the nozzle (3) in an area corresponding to the basal ejection openings (11).

11. A device according to Claim 1, in which the nozzle (3) is characterized by an angle (15) belonging to the concave truncated base of the nozzle (3) and formed by the junction of a bottom wall and an oblique lateral wall of said concave truncated base.

10

15

20

25

30

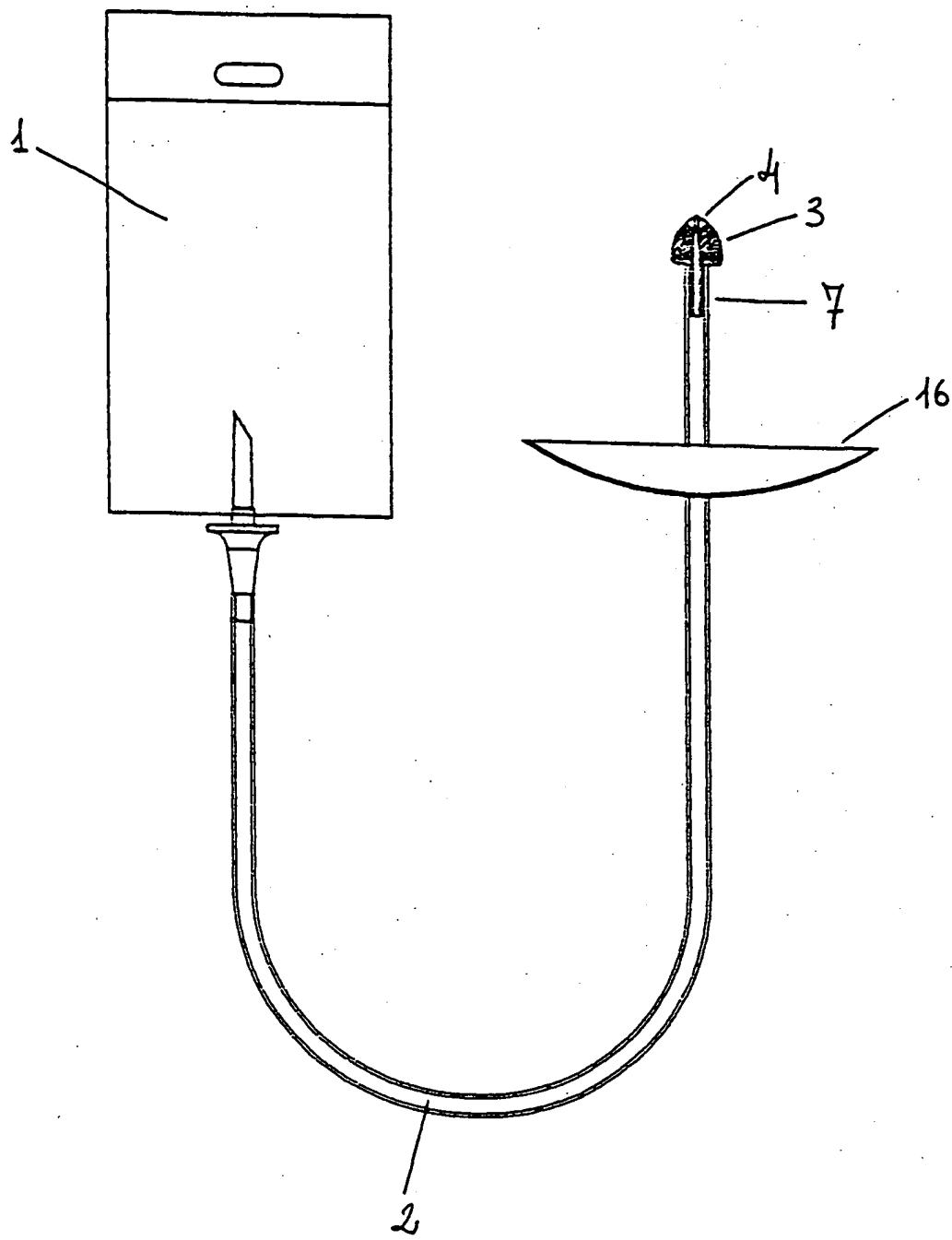
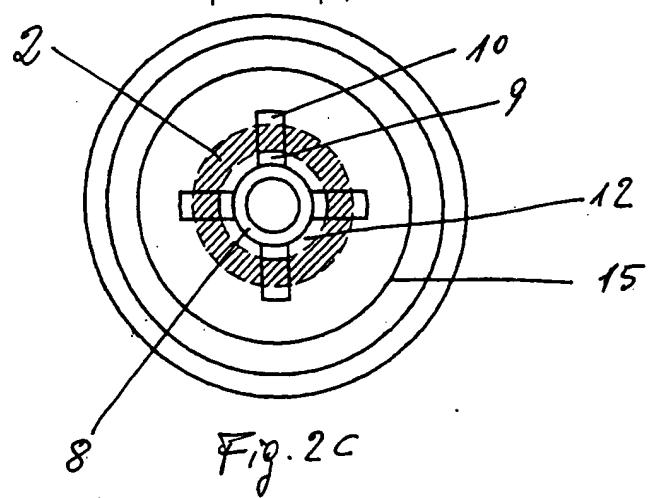
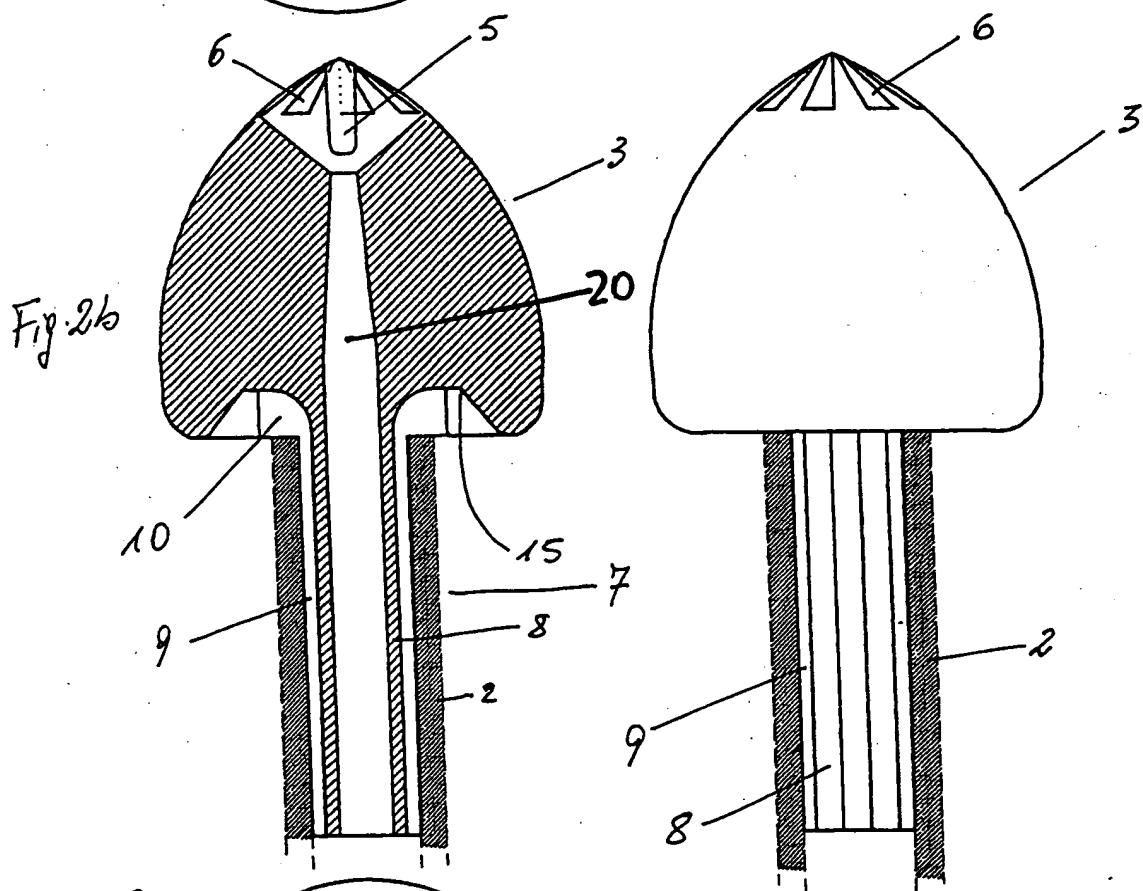
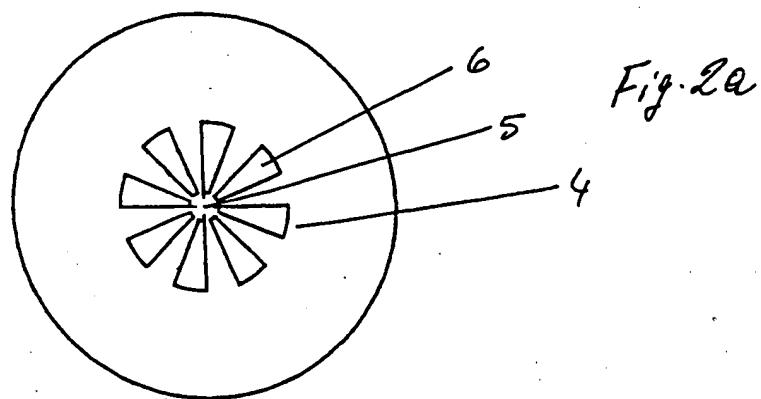
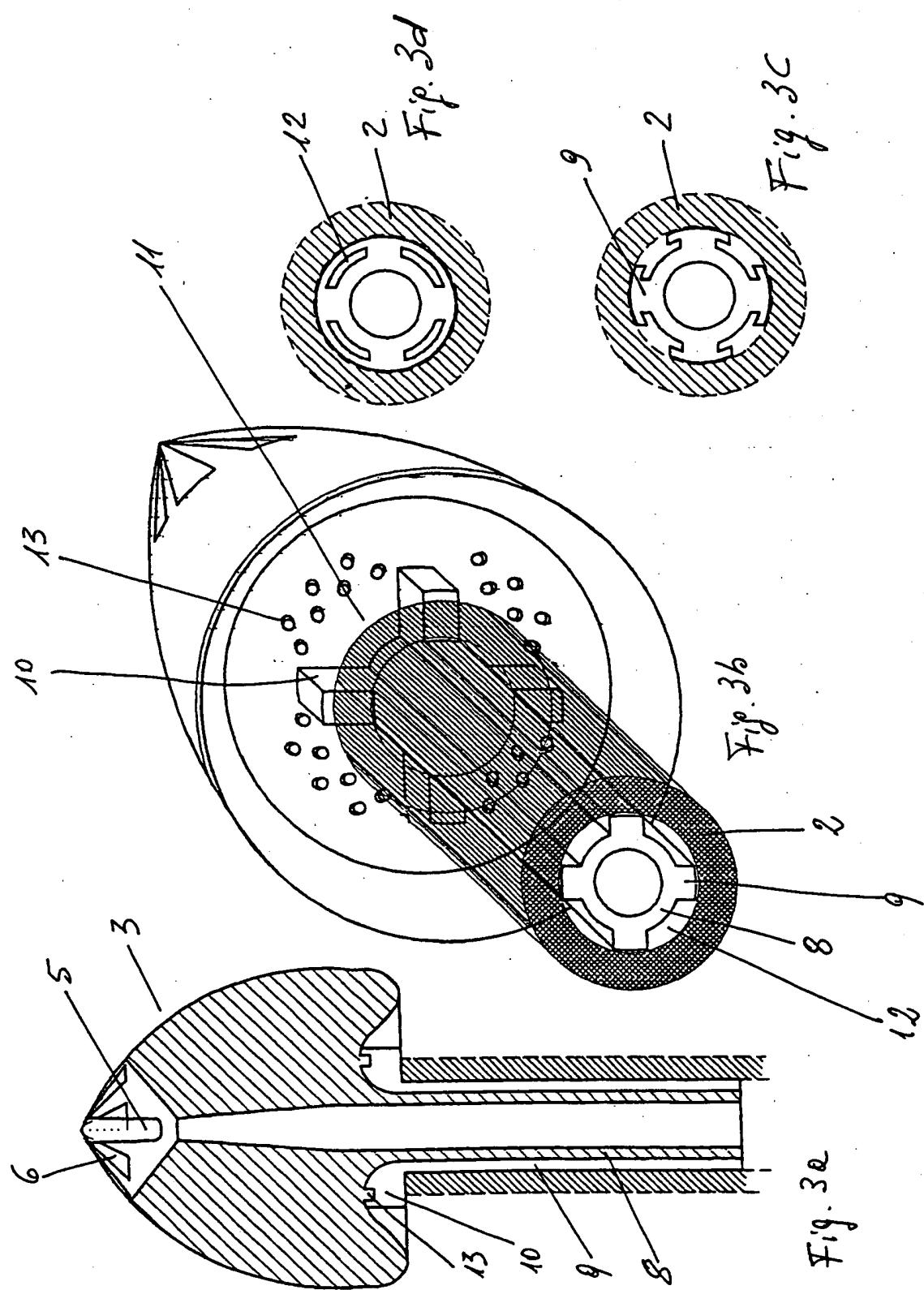


Fig 1





4/6

Fig. 4a

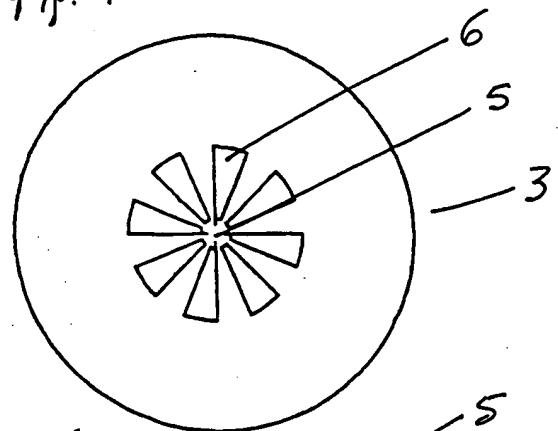


Fig. 4b

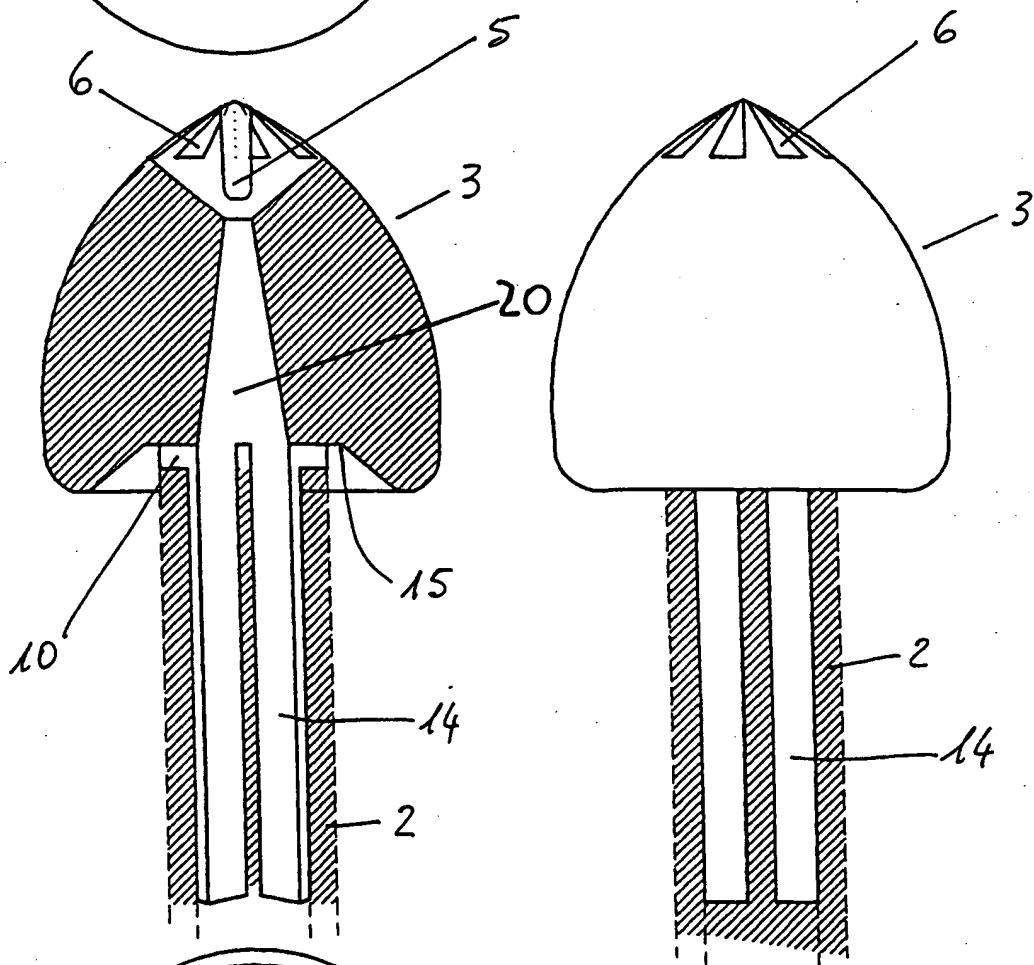


Fig. 4d

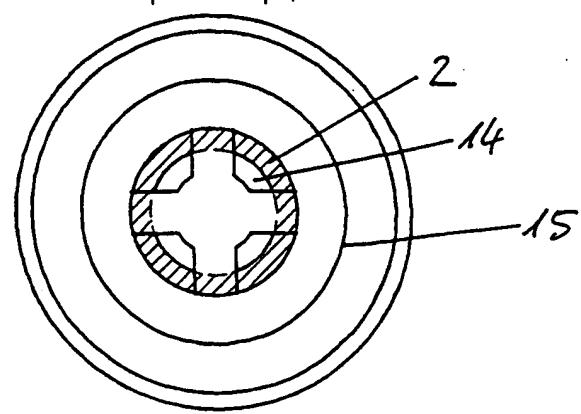
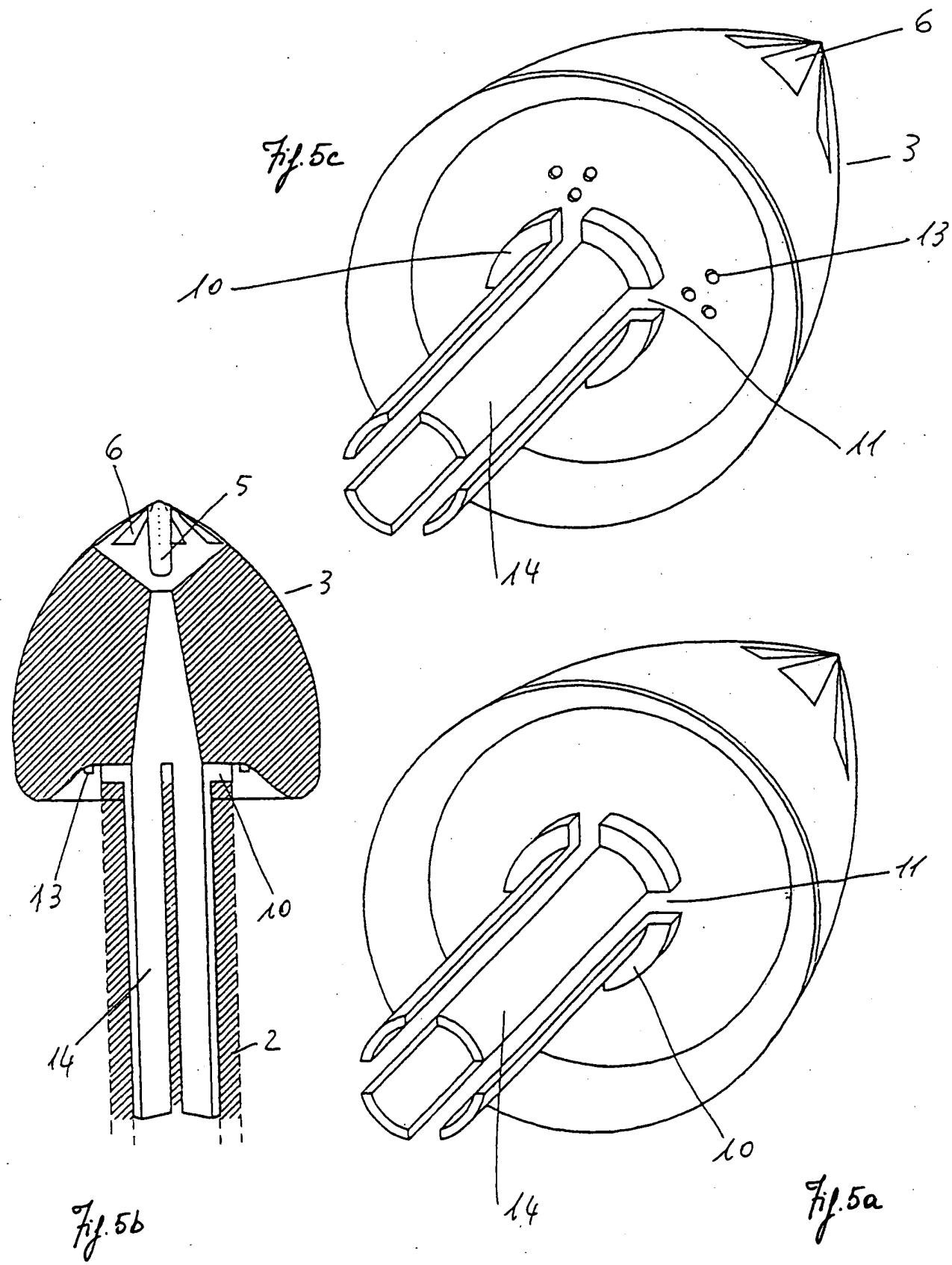
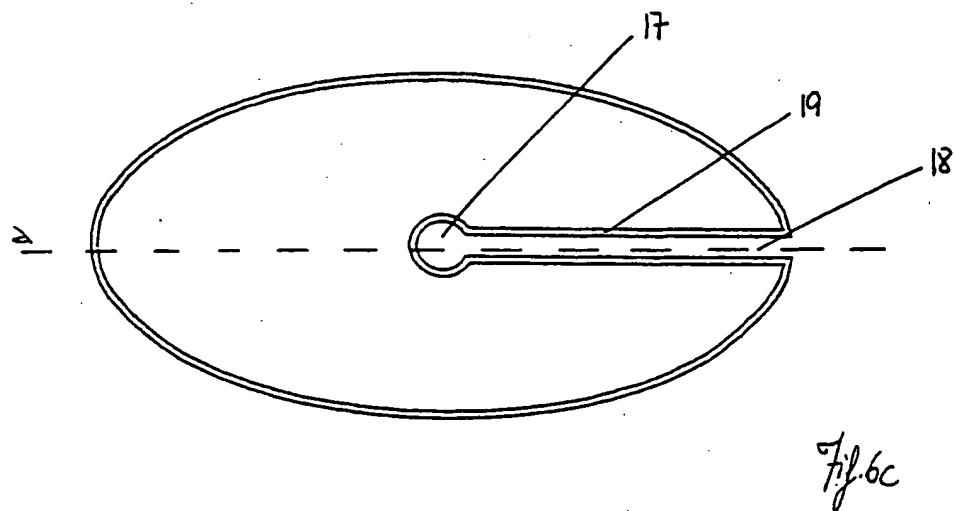
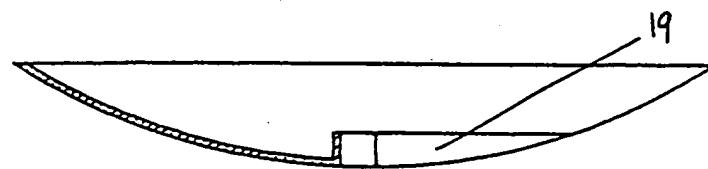
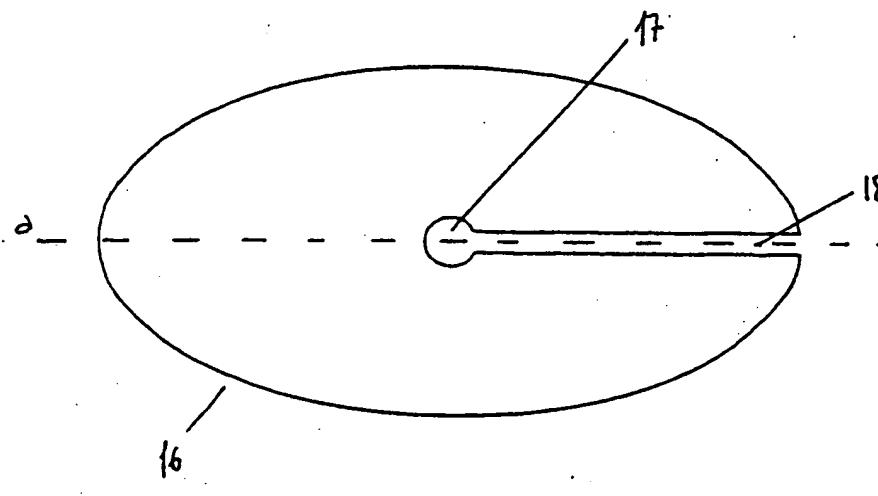


Fig. 4c



6/6



INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/09985

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M3/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 756 236 A (MURRAY ET AL.) 4 September 1973 (1973-09-04) abstract; figures 1,2 ---	1-11
A	FR 640 633 A (SCHULZ) 18 July 1928 (1928-07-18) figure 1 ---	1,10,11
A	US 2 470 293 A (D'ANGELO) 17 May 1949 (1949-05-17) figures 1,2 ---	1
A	US 4 133 313 A (SNEIDER) 9 January 1979 (1979-01-09) abstract; figures 1,3 ---	1
A	DE 637 278 C (WIRTH) figures 1,2 ---	1

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

7 February 2001

Date of mailing of the international search report

14/02/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Michels, N

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int	National Application No
PCT/EP 00/09985	

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 3756236	A 04-09-1973	AU 4863972 A		09-05-1974
		CA 1006408 A		08-03-1977
		DK 574074 A		26-05-1975
		FR 2159523 A		22-06-1973
		GB 1417005 A		10-12-1975
		GB 1417004 A		10-12-1975
		SE 393294 B		09-05-1977
		US 3871518 A		18-03-1975
		US 3847149 A		12-11-1974
FR 640633	A 18-07-1928	NONE		
US 2470293	A 17-05-1949	NONE		
US 4133313	A 09-01-1979	US 3993070 A		23-11-1976
		US 4217897 A		19-08-1980
DE 637278	C	NONE		